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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,465	04/13/2000	Robert F. Bencini	15916-261	7431

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Henricks Slavin & Holmes LLP
840 Apollo Street
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El Segundo, CA 90245

EXAMINER

SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/548,465	BENCINI ET AL.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,24,43-48,50-54,65,66 and 68-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-48,50-54 and 65, 66,68 is/are allowed.
- 6) ☒ Claim(s) 20,21,24,43,44,69,74 and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 71 is objected to because of the following informalities: claim 71 is missing. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 69 and consequently dependent claims 70 and 72-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is rather unclear what Applicant is trying to claim with the phrase "continuous length" in line 12 of claim 69. The phrase "a substantially tubular member ... defining a wall thickness and a continuous length in a direction parallel to the longitudinal axis" appears to be claiming that the tubular member has a length that is continuous with the length of the longitudinal body, which according to the drawings, is not correct. Also, it is suggested that commas be placed within the last three lines of this claim in order to make it clear that the length is greater than the wall thickness and not the longitudinal axis, as it currently reads.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 4,934,340) in view of Savage et al. (US Patent No. 5,507,725). Ebling discloses the device substantially as claimed including an apparatus (Fig. 5), comprising: an elongate body (Fig. 4, 10a) defining a proximal portion (near 14a) and a distal portion (12a) and including a wall (the wall is defined as the substance between the lumen of (18a) and the outer surface of 10a) defining an inner surface (inner surface of lumen (18a)), an outer surface (10a) and a lumen (18a) extending from the proximal portion to an aperture in the distal portion (col. 6, lines 6-9); a steering wire (20a) having a proximal portion (Fig. 4) that extends to the proximal portion of the elongate body (near 14a) and a distal portion (near 12a); and a stiffening member (22a) associated with the distal portion of the elongate body and defining a distal end; an

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anchoring member (24a) located within the wall of the distal portion (Fig. 5) of the elongate body between the inner surface and the outer surface, in contact with the wall and secured to the distal portion of the steering wire (20a) and the distal end of the stiffening member (22a); and a handle (Fig. 4, 40). Ebling further discloses an anti-tear device configured and positioned relative to the stiffening member so as to prevent the stiffening member from tearing through the elongated body when the stiffening member bends (col. 4, lines 1-5 discloses that multiple rings (24 and 24a) can be positioned throughout the catheter and be connected to the support member/stiffening member. Therefore, two of these rings, connected together by the support member constitutes the same device as the applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire; therefore, one ring positioned proximal to the distal ring (24a) shown in Fig. 5 can be attached to the stiffening member (22a) at a more proximal location, as Ebling discloses that multiple rings can be used and attached; see also col. 3, lines 41-45); Ebling also discloses that the bending assembly can be radiopaque to be used with radiographic monitoring of the position of the catheter tip (col. 5, lines 4-7).

Ebling, however, does not disclose that the handle is adapted to pull the steering wire relative to the elongate body. Instead, Ebling discloses that the steering wire is a wire that contracts when a charge is applied, and the contraction pulls the distal end of the catheter in the direction of the contraction of the steering wire. Savage, however, discloses a catheter with a handle (Fig. 1, 16) that is adapted to pull the steering wire (24a and 24b) relative to the elongate body, and further discloses that the steering wires

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are attached to anchoring ring members (Fig. 5, 22), just as the steering wire in Ebling is attached to an anchoring ring member. Therefore it would have been obvious to one of ordinary skill in the art to have modified Ebling, by applying his bending assembly, comprised of the anchoring member, steering wire and the stiffening member, to other types of steerable catheters steered by a pull wire, in order to provide the bending assembly and adapt it to other medical devices, as Ebling discloses that it can be applied to many other medical devices in which steering is needed (col. 7, lines 20-45).

Claims 24, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 4,934,340). Ebling discloses the apparatus (Fig. 5) substantially as claimed, comprising: an elongate body (Fig. 4, 10a) defining a proximal portion (near 14a) and a distal portion (12a) and including a wall (the wall is defined as the substance between the lumen of (18a) and the outer surface of 10a) defining an inner surface (inner surface of lumen (18a)), an outer surface (10a) and a lumen (18a) extending from the proximal portion to an aperture in the distal portion (col. 6, lines 6-9); a steering wire (20a) having a distal portion (near 12a); an anchoring member (24a) associated with the distal portion of the elongate body and secured to the steering wire (col. 1, line 66 through col. 2, line 3); a stiffening member (22a) associated with the distal portion of the elongate body and defining a distal end, the distal end of the stiffening member being directly secured to the anchoring member (col. 1, line 66 through col. 2, line 3); and an anti-tear device secured to the proximal end of the stiffening member and configured so as to prevent the stiffening member from tearing

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through the elongate body when the stiffening member bends (col. 4, lines 1-5 discloses that multiple rings (24 and 24a) can be positioned throughout the catheter and be connected to the support member/stiffening member. Ebling does not disclose the precise placement of the rings, but does disclose that they can be placed through out the catheter and therefore it is reasonable that at least one of the rings would be connected to the proximal end of the stiffening member. Therefore, two of these rings, connected together by the support member constitutes the same device as the applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire; see also col. 3, lines 41-45). While Ebling does not disclose that the anti-tear device is secured to the proximal end of the stiffening member (22a), as discussed above, Ebling discloses that multiple rings (24 and 24a) which form part of the anti-tear device, can be placed all along the catheter (col. 4, lines 1-5), and therefore it is obvious that at least one of those rings would be attached to the proximal end of the stiffening member. Furthermore, it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

In reference to claims 43 and 44, Ebling discloses that the anti-tear device is secured to the stiffening member and is tubular (col. 4, lines 1-10).

Claims 69 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 4,934,340) in view of Quiachon et al. (US Patent No. 6,540,778). Ebling discloses the device substantially as claimed, including an

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apparatus (Fig. 5), comprising: an elongate body (Fig. 4, 10a) defining a proximal portion (near 14a) and a distal portion (12a) and including a wall (the wall is defined as the substance between the lumen of (18a) and the outer surface of 10a) defining an inner surface (inner surface of lumen (18a)), an outer surface (10a) and a lumen (18a) extending from the proximal portion to an aperture in the distal portion (col. 6, lines 6-9); a steering wire (20a) having a distal portion (near 12a); an anchoring member (24a) associated with the distal portion of the elongate body and secured to the steering wire (col. 1, line 66 through col. 2, line 3); a stiffening member (22a) associated with the distal portion of the elongate body and defining a distal end, the distal end of the stiffening member being directly secured to the anchoring member (col. 1, line 66 through col. 2, line 3); and a substantially tubular member, secured to the stiffening member (col. 4, lines 1-5 discloses that multiple rings (24 and 24a) can be positioned throughout the catheter and be connected to the support member/stiffening member. Therefore, any one of these rings can be the tubular member).

Ebling, however, does not disclose that the dimensions of the tubular member, such as the length is greater than the wall thickness. Quiachon, however, discloses a substantially tubular member (either of 95 or 96 in Fig. 9), secured to the stiffening member (either can be the stiffening member and the other is secured to that one) defining a wall thickness and a continuous length in a direction parallel to the longitudinal axis that is substantially greater than the wall thickness (as seen in Fig. 9, both have a length that is greater than the wall thickness of the tubular member). Therefore it would have been obvious to one of ordinary skill in the art at the time of the

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invention to have modified Ebling with the longer length tubular members, as taught by Quiachon, in order to provide a tubular member that provides more longitudinal support, rather than just circumferential. Furthermore, it would have been obvious since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

In reference to claim 75, Ebling discloses that the steering wire extends to the proximal portion of the elongate body and is movable relative to the proximal portion of the elongate body (col. 3, lines 20-24).

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 4,934,340) in view of Quiachon et al. (US Patent No. 6,540,778) and further in view of Savage et al. (US Patent No. 5,507,725). Ebling in view of Quiachon disclose the device substantially as claimed except that Ebling in view of Quiachon does not disclose that the handle is adapted to pull the steering wire relative to the elongate body. Instead, Ebling in view of Quiachon discloses that the steering wire is a wire that contracts when a charge is applied, and the contraction pulls the distal end of the catheter in the direction of the contraction of the steering wire. Savage, however, discloses a catheter with a handle (Fig. 1, 16) that is adapted to pull the steering wire (24a and 24b) relative to the elongate body, and further discloses that the steering wires are attached to anchoring ring members (Fig. 5, 22), just as the steering wire in Ebling is attached to an anchoring ring member. Therefore it would have been obvious to one

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of ordinary skill in the art to have modified Ebling in view of Quiachon, by applying his bending assembly, comprised of the anchoring member, steering wire and the stiffening member, to other types of steerable catheters steered by a pull wire, in order to provide the bending assembly and adapt it to other medical devices, as Ebling in view of Quiachon discloses that it can be applied to many other medical devices in which steering is needed (col. 7, lines 20-45).

Response to Arguments

Applicant's arguments with respect to claims 20, 21, 24, 43, 44, 69, 74 and 75 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 70, 72 and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 45-48, 50-54 and 65-68 are allowed. Claims 45-48, 50-54 and 65-68 distinguish themselves over the prior art as the prior art does not suggest an anti-tear device with a slot in it and which is not connected to the steering wire.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

